K140095

SECTION 5 – 510(k) SUMMARY or 510(k) STATEMENT

MAY 2 0 2014

510(k) Summary

Stryker Corporation – Medical Division

Prime Series® Stretcher with Zoom® Motorized Drive

SUBMITTER/510(K) HOLDER

Name:	Stryker Corporation – Medical Division
Address:	3800 East Centre Ave. Portage, MI 49002
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Date Prepared:	11 March 2014

DEVICE NAME

Proprietary Name:	Prime Series® Stretcher with Zoom® Motorized Drive
Catalog Numbers:	1125
Common/Usual Name:	Patient Transport Stretcher
Classification Name:	Powered Wheeled Stretcher
Classification:	21 CFR 890.3690
Product Code:	INK
Classification Panel:	Physical Medicine

PREDICATE DEVICES

Stryker Medical ("Stryker") claims substantial equivalence to:

1. Stryker Powered Wheeled Stretcher (K022309)

DEVICE DESCRIPTION

The Prime Series® Stretcher with Zoom® Motorized Drive, is a powered wheeled stretcher that consists of a platform mounted on a wheeled frame that is designed to transport patients in a substantially horizontal position within the interior of a healthcare facility by health professionals and/or trained representatives of the user facility. The electric-drive system, called the Zoom Drive System, assists the health professional and/or trained representative by assisting stretcher movement and maneuverability in various healthcare facilities. The device can be manually pushed by the user in the event of power loss to the Zoom Drive System. The device has siderails, supports for fluid infusion equipment, and various options and accessories that assist with the transport of the patient. The Prime X option is intended to provide an articulating radiographic patient support surface and a platform below the patient support surface for x-ray cassette placement to assist in the capture of clinical x-rays when used in conjunction with a medical x-ray system.

INTENDED USE

The Prime Series® Stretcher with Zoom® Motorized Drive is an electromechanical stretcher that provides a method of transporting patients within healthcare facilities. The stretcher may be used for minor procedures and short-term stay, typical of existing stretcher applications, such as short-term outpatient clinical evaluation, treatment, minor procedure, and as a short-term outpatient recovery platform. The drive-assist Zoom® feature provides a healthcare professional and/or trained representative greater maneuverability in steering and moving the stretcher with significantly less force. The Prime Series® Stretcher with Zoom® Motorized Drive is intended for use in all establishments and may include use in, but not limited to, the Emergency Department (ED), including the Trauma area, and Postanesthesia Care Unit (PACU). The Prime Series® Stretcher with Zoom® Motorized Drive has a safe working load up to 700 pounds (318 kg) and is intended to support and transport all patients, including those mildly to critically ill. The Prime Series® Stretcher with Zoom® Motorized Drive may also be used to transport deceased patients within an enclosed healthcare facility.

The Prime X option is intended to provide an articulating radiographic patient support surface and a platform below the patient support surface for x-ray cassette placement to assist in the capture of clinical x-rays when used in conjunction with a medical x-ray system.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on one predicate device, Stryker Power Wheeled Stretcher (K022309). The referenced predicate device is a powered wheeled stretcher as defined in 21 CFR § 890.3690. The product code of the cleared predicate device is INK.

Like the predicate device, the Prime Series® Stretcher with Zoom® Motorized Drive is a DC powered wheeled stretcher that operates as an electromechanical stretcher which provides a method of transporting patients within healthcare facilities. The Prime Series® Stretcher with Zoom® Motorized Drive may be used for minor procedures and short-term stay, typical of existing stretcher applications. The drive-assist Zoom® system provides the healthcare professional and/or trained representative greater maneuverability in steering and moving the stretcher with significantly less force. The Prime Series® Stretcher with Zoom® Motorized Drive is equivalent in operational characteristics to the predicate device in that the mobility, drive-assist Zoom® system, and caregiver input for patient transport operate in the same manner. Both devices have a four (4) caster brake system, side rails, hydraulic lift system for height adjustment, support, and trendelenburg features of the patient surface. Both devices also feature similarities in construction materials and surface mattresses.

The Prime Series® Stretcher with Zoom® Motorized Drive includes an available option that allows for a full-length articulating radiographic patient support surface and platform. A dual-deck design of the patient platform allows for the positioning of x-ray cassettes at any point under the patient, from head to foot and side to side. With an open architecture design, this design will accommodate the majority of sizes of commercially available x-ray cassette receptors. The predicate device featured an optional x-ray cassette holder behind the fowler portion of the patient platform. Verification and validation of design and performance for the Prime Series® Stretcher with Zoom® Motorized Drive demonstrates that these technology differences do not adversely affect safety and effectiveness of the device when used as labeled, as the device has been fully tested for use and performance to demonstrate its safe and effective use.

Table 5-1 Side-by-Side Comparison of Prime Series® Stretcher with Zoom® Motorized Drive with Predicate Device

Category	Subject Device: Prime Series® Stretcher with Zoom® Motorized Drive	Predicate Device: Stryker Powered Wheeled Stretcher K022309
Indications for Use	The Prime Series® Stretcher with Zoom® Motorized Drive is an electromechanical stretcher that provides a method of transporting patients within healthcare facilities. The stretcher may be used for minor procedures and short-term stay, typical of existing stretcher applications, such as short-term outpatient clinical evaluation, treatment, minor procedure, and as a short-term outpatient recovery platform. The drive-assist Zoom® feature provides a healthcare professional and/or trained representative greater maneuverability in steering and moving the stretcher with significantly less force. The Prime Series® Stretcher with Zoom® Motorized Drive is intended for use in all establishments and may include use in, but not limited to, the Emergency Department (ED), including the Trauma area, and Postanesthesia Care Unit (PACU). The Prime Series® Stretcher with Zoom® Motorized Drive has a safe working load up to 700 pounds (318 kg) and is intended to support and transport all patients, including those mildly to critically ill. The Prime Series® Stretcher with Zoom® Motorized Drive may also be used to transport deceased patients within an enclosed healthcare facility. The Prime X option is intended to provide an articulating radiographic patient support surface and a platform below the patient support surface for x-ray cassette placement to assist in the capture of clinical x-rays when used in conjunction with a medical x-ray system.	The Stryker Powered Wheeled Stretcher is an electromechanical stretcher that provides a method of transporting patients within healthcare facilities. The stretcher may be used for minor procedures and short-term stay, typical of existing stretcher applications. The drive-assist Big Wheel provides the healthcare caregiver greater maneuverability in steering and moving the stretcher with significantly less force.
Product Weight	416 – 483 lbs.	Less than 450 lbs.
Patient Capacity	700 lbs. max	500-700 lbs. max
Overall Dimensions	Length: 86" Width: 31" to 34"	Length: 84" Width: 31" to 34"
Patient Surface Dimensions	Length: 75.25" Width: 26" or 30"	Length: 75.5" Width: 26" to 29"
Height Range (to litter top):		

- High **- Low**	37.25" 26.25"	35.5" – 36" 21" – 22"
Trendelenburg/ Reverse Trendelenburg	+/- 16 degrees	+/- 16 degrees
Articulation: **- Fowler (electric)** **- Fowler (manual)** **- Knee Gatch**	 Available option, not in conjunction with Prime X option 0-90 degrees 0-40 degrees, not in conjunction with Prime X option	 None 0 – 90 degrees 0 – 35 degrees
Siderails - Length - Height - In-Rail Controls - Patient Lock-out	Glideaway collapsible siderails 54" 12" (Prime X Option); 14" Available option, not in conjunction with Prime X option Available option, not in conjunction with Prime X option	Glideaway collapsible siderails 54" 14" None None
Lift System	Manual Hydraulic pedestal jacks	Manual Hydraulic pedestal jacks
Brake and Steer	Located at head/foot end 4 caster brake system	Located at head/foot end 4 caster brake system
Mobility **- Zoom Drive** **- Push Control Handles** **- Performance on Ramps (Grades)** **Zoom Drive Speed**	 Drive-assisted "Big Wheel" – controlled by the caregiver Electrical push handles used to maneuver loaded/unloaded stretcher Drive-assisted "Big Wheel" will aid the healthcare user Healthcare user sets the speed of the stretcher using the push control handles	 Drive-assisted "Big Wheel" – controlled by the caregiver Electrical push handles used to maneuver loaded/unloaded stretcher Drive-assisted "Big Wheel" will aid the healthcare user Healthcare user sets the speed of the stretcher using the push control handles
Casters **- Diameter** **- Casters**	 8" Covered	 8" Covered/Uncovered available
Mattress	3" h (standard), 4", & 5" h optional (5" not available in conjunction with Prime X option)	3" h (standard), 4" & 5" h (optional)
Energy Source – Charging System	120 V, 60Hz, 4 A	120 V, 60Hz, 4 A
Energy Source – Battery	2 x 12 V, 31Ah Battery	2 x 12 V, 31Ah Battery
Materials **- Stretcher** **- Mattress**	 Cold Rolled Steel, Hot Rolled Steel, HDPE Plastic, Glass Filled Polypropylene Plastic, ABS Plastic, Rigid PU Foam, Aluminum, Powdercoat paint Polyurethane foam with vinyl or	 Low Carbon Steel, Fiber-Resin or Low Carbon Steel Litter Panels, Siderails are chrome-plated low carbon steel with plastic or low carbon steel toprail. Polyurethane foam with vinyl or polyurethane-

	polyurethane-coated nylon covering.	coated nylon covering.
Manual Overrides	All manual overrides	All manual overrides
Standard Operating Conditions **- Storage** **- Operation**	Temp: -4°F to +140°F, Rel Humidity – Up to 95% Temp: 50°F to 100°F, Rel Humidity – 30% to 75% RH	Temp: -32°F to +140°F, Rel Humidity – Up to 100% (non-condensing) Temp: 60°F to 100°F, Rel Humidity – 0% to 60% RH (non-condensing)
Sterility	Device is not intended to be sterilized	Device is not intended to be sterilized
X-Ray Surface	Articulating radiographic patient support surface and platform	Optional radiolucent surface via X-Ray Cassette Holder (Fowler)

SUMMARY

Stryker Medical has verified and validated that the Prime Series® Stretcher with Zoom® Motorized Drive meets its functional, performance, safety, and efficacy specifications and requirements. Physical and mechanical testing has been performed on individual components and on the system, including Software testing that has been completed. The Prime Series® Stretcher with Zoom® Motorized Drive has successfully passed bench and software testing. Test results demonstrate that both the individual units and system meet specified performance requirements.

The Prime Series® Stretcher with Zoom® Motorized Drive has been designed and evaluated according to the following FDA Recognized and international Standards:

- AAMI/ANSI/ISO 10993-1: 2009; Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a Risk Management Process
- ISO 10993-2: 2006; Biological Evaluation of Medical Devices -- Part 2: Animal Welfare Requirements
- AAMI/ANSI/ISO 10993-5: 2009; Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- AAMI/ANSI/ISO 10993-10: 2010; Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-11: 2006; Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity
- AAMI/ANSI ES 60601-1: 2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 ; Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 3:2007-03; Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-3 Edition 2.0 2008-01, Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment

- IEC 60601-2-52 Edition 1.0 2009-12, Medical Electrical Equipment - Part 2-52: Particular Requirements For Basic Safety And Essential Performance Of Medical Beds

- IEC 60601-2-54 Edition 1.0 2009-06, Medical Electrical Equipment - Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Radiography And Radioscopy

Based on the Prime Series® Stretcher with Zoom® Motorized Drive and predicate design, operational and technical characteristics and completed bench testing, the Prime Series® Stretcher with Zoom® Motorized Drive is substantially equivalent to and as safe and effective as that of the predicate device. The Prime Series® Stretcher with Zoom® Motorized Drive's intended uses are substantially supported by the previously cleared predicate device. Any differences described between the Prime Series® Stretcher with Zoom® Motorized Drive and the predicate device does not raise any new issues of safety or effectiveness. The Prime Series® Stretcher with Zoom® Motorized Drive's indication for use statement includes all of the same indications as the previously cleared predicate device.

CONCLUSION

In summary, Stryker Medical has demonstrated that the Prime Series® Stretcher with Zoom® Motorized Drive is as safe and effective as and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2014

Stryker Corporation – Medical Division
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K140095
Trade/Device Name: Prime Series® Stretcher with Zoom® Motorized Drive
Regulation Number: 21 CFR 890.3690
Regulation Name: Powered Wheeled Stretcher
Regulatory Class: Class II
Product Code: INK
Dated: March 19, 2014
Received: March 28, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140095

Device Name
Prime Series® Stretcher with Zoom® Motorized Drive

Indications for Use *(Describe)*
The Prime Series® Stretcher with Zoom® Motorized Drive is an electromechanical stretcher that provides a method of transporting patients within healthcare facilities. The stretcher may be used for minor procedures and short-term stay, typical of existing stretcher applications, such as short-term outpatient clinical evaluation, treatment, minor procedure, and as a short-term outpatient recovery platform. The drive-assist Zoom® feature provides a healthcare professional and/or trained representative greater maneuverability in steering and moving the stretcher with significantly less force. The Prime Series® Stretcher with Zoom® Motorized Drive is intended for use in all establishments and may include use in, but not limited to, the Emergency Department (ED), including the Trauma area, and Postanesthesia Care Unit (PACU). The Prime Series® Stretcher with Zoom® Motorized Drive has a safe working load up to 700 pounds (318 kg) and is intended to support and transport all patients, including those mildly to critically ill. The Prime Series® Stretcher with Zoom® Motorized Drive may also be used to transport deceased patients within an enclosed healthcare facility.

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.20 15:38:03 -04'00'

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